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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,514	03/31/2004	John R. Gilbert	TGZ-030	9911
959	7590	04/18/2005	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			MENON, KRISHNAN S	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 04/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/816,514

Applicant(s)

GILBERT ET AL.

Examiner

Krishnan S. Menon

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5, 8, 19-44, 51 and 53-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 7, 9, 11-18, 45-52 and 59 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1-59 are pending, of which claims 4,5,8,19-44, 51 and 53-58 are withdrawn from consideration by election of 2/25/05

### ***Election/Restrictions***

Applicant's election with traverse of claims 1-18, 46-52 and 59 in the reply filed on 2/25/05 is acknowledged. The traversal is on the ground(s) that the groups of claims are not directed to independent or distinct inventions and that there is no serious burden to search. This is not found persuasive because the claimed subject matter is different in each group, the groups belong to different class/subclasses and the search required for each of the group is different from the other groups. Powerful computers and search engines do not eliminate the requirement of the class/sub class search. 'A molecular fractionation device' cannot be considered a single searchable unifying feature because that phrase has an overwhelmingly great scope ranging from petroleum processing to sewage treatment.

With respect to the species election, a statement that they 'are not patentably distinct features' is insufficient to overcome the restriction requirement. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the

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evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The requirement is still deemed proper and is therefore made FINAL.

Applicant has elected the species 'affinity beads', but has not indicated the claims that belong to the non-elected species. Therefore, the Examiner has made the determination that claims 4,5,8 and 51 belong to a non-elected species, and claims 4,5,8 and 51 are also withdrawn from further consideration.

Claim 45 was inadvertently left out in the election/restriction requirement, which is included in the elected group I.

Thus, Claims 4,5,8,19-44, 51 and 53-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention/species, there being no allowable generic or linking claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3,6,7,9, 11-18 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilding et al (US 5,498,392).

Claims 1,17 and 59: Wilding teaches a microfluidic system or a molecular fractionation device (figures 3-10) microchannels ((54,56,57) on substrate (50),

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communication ports (51,59,) and capping module (10) having an affinity matrix and a trapping filter (92, 24: see fig 10) for compartmentalizing the matrix, capping module is stacked on to the substrate (figures).

Claims 2 and 3: affinity beads with binding sites – col 14 lines 38-60

Claims 6, 7: capping module includes chamber for the matrix and connector ports – fig 10

Claim 9: the filter is a semipermeable membrane – impermeable to the matrix.

Claim 11: see figures 3,10 etc for the capping module with substrate, matrix and the filter.

Claim 12: recess – 22C, filter 24 covers the recess – fig 6, 10.

Claim 13: chamber – 22C, port – 20 C or 16 D, filters 24 cover the ports

Claim 14: substrate includes first and second connector ports – see figures.

Claim 15: 4 different ports for the chamber in the capping module 10 – 16 A-D.

Claim 16: different combination of fluid flow paths with the ports can be seen in figures 10,11 and 12.

Claim 18: matrix insertion port – the matrix can be inserted before the assembly of 10 to the device 50 (fig 6); the opening of the chamber 22C would be the matrix insertion port.

2. Claims 45-48 and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Geli (US 2003/0027354).

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Claim 45: Geli teaches plurality of the molecular fractionation devices in the microfluidic system coupled in series so that outlet of one is inlet of the next, the device includes a matrix having an affinity for a selected molecule (chromatographic column) – see figure 3,4: fractionation microcolumn 2, primary micro channel 3, secondary microcolumn 10, detection zone with channels 12 and 13. (paragraphs 65 – 94).

Claim 46: release channels – 6 or 15

Claim 47: second outlet, etc – 15.

Claim 48: second inlet – 8.

Claim 52: ejection component – through line 8.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 45-50 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding'392 in view of Geli (US 20030027354 A1).

Wilding teaches all the limitations of claim 45 – microfluidic system having a first channel, and molecular fractionation device with a matrix having affinity for select molecules and inlet and outlet – see figures, especially 6 and 10.

Wilding does not teach plurality of such devices coupled in series with outlet of the first as inlet for the second. Geli teaches such an arrangement – figures 3 and 4,

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wherein the outlet of the first microcolumn (2) is connected to the inlet of the second (10). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Geli in the teaching of Wilding for analysis of proteins from biological samples, study of functional expression of genes, etc., as taught by Geli (paragraph 1 and 2), with amplification as taught by Wilding (abstract).

Claim 46-48: release channels, inlets and outlets – see figures of Wilding.

Claims 49 and 50: filter – 24, Wilding. Capping module with a membrane (10).

Claim 52: ejection component – Geli, through line 8-fig 3 and 4.

### ***Allowable Subject Matter***

Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The closest prior arts are Wilding'392 and Geli'354. Both references do not teach or suggest having a semipermeable membrane as a trapping filter for compartmentalizing the matrix with the membrane covered by an impermeable layer except for the first and second connection ports.

### ***Conclusion***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Krishnan S. Menon  
Patent Examiner  
4/1/05

  
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